

### **REMARKS / ARGUMENTS**

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration claims 2, 4, 6, 7, 9, 11, 13, and 14 remain unchanged, and claims 1, 3, 5, 8, 10, and 12 have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a system for increasing the concentration of a gaseous or vapor phase sterilant in a sterilization or decontamination system. The decontamination system of the present invention includes a closed loop system for supplying vaporized hydrogen peroxide to a region. In one embodiment, the closed loop system includes a first flow path having a generator for generating vaporized hydrogen peroxide and a destroyer disposed therein. Carrier gas conveys VHP along the first flow path through the destroyer and the generator. The closed loop system of the present invention also includes a bypass conduit that defines a second fluid flow path. Carrier gas and VHP flowing along the second fluid flow path bypasses the destroyer and flows through the generator.

During a conditioning phase, a generator is used to generate VHP and to introduce the VHP into the circulation system. The present invention provides a decontamination system that *increases the rate* at which the concentration of VHP can be increased within a room or isolator during the conditioning phase. As disclosed in paragraph [0028] of the specification of the present application, VHP flows only along the second fluid flow path during the conditioning phase. In this regard, all of the vaporized hydrogen peroxide generated by the generator bypasses the destroyer during the conditioning phase.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a circulation system having a first fluid flow path and a second fluid flow path as presently set forth in the claims, or the advantages thereof.

In response to the Examiner's rejections, claims 1, 3, 5, 8, 10, and 12 have been amended. Claim 1 has been amended to indicate that a controller is operable to cause

*substantially all of* said vaporized hydrogen peroxide generated by said generator to bypass the destroyer.

Claims 1 and 5 have been amended to indicate that the bypass conduit has a first end fluidly connected to the first fluid path between the region to be decontaminated and the destroyer and a second end fluidly connected to said first flow path between said destroyer and said generator.

Claim 5 has also been amended to indicate that *substantially all of* the vaporized hydrogen peroxide generated by said generator bypasses said destroyer.

Claim 10 has been amended to indicate that the bypass conduit is for directing the carrier gas flow through the closed loop system and *only* through a second fluid path around the destroyer. Claim 10 has been amended to indicate that the bypass conduit has one end connected to the first fluid path between the destroyer and an outlet port.

The Examiner has rejected claims 1-5 and 7-14 under 35 U.S.C. 103(a) as being unpatentable over PCT International Publication No. WO01/21223 A1 to Martin et al. in view of U.S. Patent No. 5,906,794 to Childers. The Martin et al. reference discloses an apparatus for sterilizing a sealable enclosure that includes a fluid circuit that has two "parallel branches." A "first parallel branch" contains means to deactivate a sterilant, i.e., the destroyer, and means to dehumidify the carrier gas. A "second parallel branch" contains means to heat the gas and means to supply a sterilant vapor or vapors, i.e., the generator, to the carrier gas.

The method of sterilizing disclosed by the Martin et al. reference includes the following three steps that are executed in order: (1) reducing the relative humidity in the enclosure; (2) circulating the carrier gas containing the sterilant; and (3) removing the sterilant from the enclosure. The destroyer is only operated during the third step and is used to completely remove sterilant from the carrier gas.

The Childers reference discloses a method and system for conducting a continuous operation, closed loop, flow-through vapor phase decontamination. The Childers reference discloses a system for vaporizing a liquid decontaminant and delivering the vaporized decontaminant into, through, and out of a sealable chamber through a closed loop conduit circuit. The system includes a first flow path and a second flow path. A first fluid flow line connects the

first flow path to a dryer. A converter for destroying VHP and a generator for generating VHP are disposed along the first flow path. A second fluid flow line defines the second flow path around the dryer. A three-way valve is provided for varying the distribution of flow between the first flow path and the second flow path. In other words, *the flow is split* between the first flow path and the second flow path. In this manner, the degree of drying can be selected to achieve a desired humidity within the chamber. Thus, the Childers reference teaches a variable bypass around *a dryer*. The Childers reference does not teach, suggest, or show a bypass conduit that causes *substantially all* sterilant generated by the generator to bypass *a destroyer*.

Neither the Martin et al. reference nor the Childers reference teaches, suggests, or shows a vapor decontamination system for decontaminating a defined region that includes a bypass conduit around a destroyer as required by claims 1, 5, and 10.

Neither reference teaches, suggests, or shows “a controller operable to cause *substantially all* of said vaporized hydrogen peroxide generated by said generator to bypass said destroyer during a predetermined phase of operation,” as required by claim 1. Neither reference teaches, suggests, or shows a bypass conduit for causing fluid to flow through said closed loop system “such that *substantially all* of said vaporized hydrogen peroxide generated by said generator bypasses said destroyer,” as required by claim 5. Further, neither reference teaches, suggests, or shows “a bypass conduit for directing said carrier gas flow through said closed loop conduit system and *only* through a second fluid path around said destroyer,” as required by claim 10. Neither the Martin et al. reference nor the Childers reference teaches, suggests, or shows a bypass conduit around a destroyer wherein the bypass conduit has a first end fluidly connected to the first fluid path between the region to be decontaminated and the destroyer as required by claims 1 and 5. Further, neither reference teaches a bypass conduit having one end connected to the first fluid path between the destroyer and an outlet port as required by claim 10.

Applicants respectfully submit that the Examiner does not explain the motivation for one skilled in the art to substitute the destroyer of the Martin et al. reference for the dryer of the Childers reference. To make a *prima facie* case for obviousness, the Examiner must identify the teaching, suggestion, or motivation to combine or modify the teachings of the prior art to

produce the claimed invention. This rule is the first of three required criteria for a *prima facie* case of obviousness set forth in § 2143 of the MPEP:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Further, a PTO rejection for obviousness is improper when there is nothing in the cited prior art references, either singly or in combination, to suggest the desirability of the claimed subject matter. *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986). The Examiner can satisfy the burden of showing obviousness only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

Applicants respectfully submit that the Examiner has not shown any teachings to combine the prior art. The Examiner stated in the Office Action mailed March 28, 2006, that it would have been obvious to configure the converter/sterilant destroyer of Martin et al. as the air dryer in Childers is configured because such a configuration would provide for optimized recycling of the sterilant and provide accurate control of the concentration of the sterilant. Maintaining optimum concentrations of the sterilant is not directly relevant to the present invention and therefore would not motivate one skilled in the art to combine the teachings of Martin et al. and Childers. As stated above, the purpose of the present invention is to increase the concentration of VHP during a conditioning step. It is not to *maintain* an optimum concentration. Accordingly, Applicants respectfully request that the Examiner identify the

teaching, or suggestion, to combine the teachings of the cited references to make the present invention.

To summarize, the present invention is directed to a system for increasing the concentration of a gaseous or vapor phase sterilant in a sterilization or decontamination system. The decontamination system of the present invention includes a closed loop system for supplying vaporized hydrogen peroxide to a region. In one embodiment, the closed loop system includes a first fluid path having a vaporized hydrogen peroxide generator and a destroyer disposed in series therein. The destroyer is disposed upstream of the generator. A bypass conduit defines a second fluid path. When flowing along the second fluid flow path, *all* fluid bypasses the destroyer and flows through the generator. All fluid either flows in the first fluid flow path or the second fluid path. The Applicants respectfully submit that the cited references do not teach, suggest, or show a circulation system having a bypass conduit around a destroyer as currently claimed.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teaches, suggests, or shows the Applicants' invention as defined by the present claims.

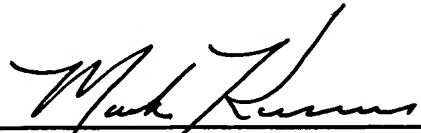
In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

Application No. 10/690,239  
Amendment dated July 13, 2006  
OUTSTANDING OFFICE ACTION dated March 28, 2006

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8723US.

Respectfully submitted,

Date: July 13, 2006

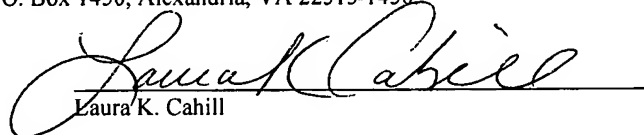
  
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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 13, 2006

  
Laura K. Cahill